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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,167	11/07/2000	Maurice Maloney	9369-161	8170

1059 7590 07/20/2004

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

919

Office Action Summary

Application No.

09/707,167

Applicant(s)

MALONEY ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20,22-30,32,34 and 35 is/are rejected.
- 7) ☒ Claim(s) 30-35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 18, 20 and 22-35 are pending.

Applicants' amendment filed 25 June 2004, which amends claims 18, 22-23, 26 and 28-29 has been entered.

The following Office Action is applicable to the pending claims 18, 20 and 22-35.

Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 20 and 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 appears to be missing a step which refers to how the oil bodies are accessible to target molecule or/and the recombinant polypeptide in order to allow the oil bodies to contact with the target molecule and a ligand protein, e.g., by expressing the recombinant protein in the cell and disrupting the cell's integrity (see claim 18, item 1). Please note that claim 18 is directed to a method of isolating a recombinant polypeptide from a cell; thus, the claim must clarify how to make contacting the oil bodies with the ligand and the recombinant polypeptide. See also claim 22, item c, which is also missing the step indicated above. The dependent claims are also rejected.

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Claim 26 is unclear in “the target molecule” because the claim does not make it clear as to whether or not said target molecule refers to a recombinant polypeptide to be isolated or an oil-body protein. Note that the specification defines the “target molecule” as the molecule that one wants to purify, which can be recombinantly produced or obtained from natural source (see page 10). See also claim 29. The dependent claims are also rejected.

The applicants' response to the rejection under 354 112, the second paragraph

The response filed 25 June 2004 argues that the contacting the oil bodies with the recombinantly expressed polypeptide has been taught in the specification; thus, the skilled artisan would understand the phrase “contacting the oil bodies with the recombinant polypeptide” (see page 7 of the response). The applicants' argument is found to be not persuasive because the specification definition or description cannot substitute what is missing in the claims. Please note that the claim must have sufficient particularity and distinctness by its own; although operational characteristics, e.g., disrupting cell's integrity which is necessary for allowing the oil bodies to contact with the recombinantly expressed polypeptide, may be apparent from specification, will not be read into the claim.

The Claim Rejections under 35 USC § 102 and § 103 are withdrawn in light of the applicants' amendments to the claims.

Provisional Rejection - Obviousness Type Double Patenting

Claims 18, 20, 29-30, 32 and 34-35 of this application conflicts with claims 15, 9-10 and 15-16 of Application No. 10260562. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18, 20, 29-30, 32, and 34-35 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-5, 9-10 and 15-16 of Application

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No.10260562. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 and 10 of 10260562 sets forth a method of isolating a target (recombinant) molecule from a cell sample comprising (i) contacting oil bodies with a protein ligand fused to an oil-body protein (claim 4) and the target molecule in the sample; and (ii) separating the form target molecule associated oil bodies from said sample (claim 1). Since said ligand is not normally associated with oil bodied, and since said ligand associates with the oil bodies and said target molecule, *e.g.*, thrombin (see claim 2-5 and 10), 10260562 claims 1-5 are obvious variation of claim 18 and 29 of the current application.

Claim 16 of 10260562 sets forth that the ligand is an antibody, which is a common subject matter of claims 20 and 30 of the current application.

Claim 15 of 10260562 teaches that the sample is a cellular sample (see [0139] and [0142]); thus, the 10260562 claims 1-5 are obvious variation of claim 32 of the current application.

Since 10260562 teach that the cell (*e.g.*, transgenic plant cell) from which the target molecule is isolated is subject to homogenization (see [0096]), *i.e.*, disrupting cell's integrity,

10260562 claim 15 is an obvious variation of claim 34 of the current application.

Claim 9 of 10260562 sets forth that the target molecule is protein, which is the subject matter of the instant claim 35.

Therefore, the instant application and Application 10260562 claims are obvious variation, and they are not patentably distinct from each other.

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It is noted that page 13 of the response filed 25 June 2004 requests abeyance of the obvious-type double patenting rejection until allowable subject matter is indicated. Note that no allowable subject matter can be indicated with a standing ground of rejection. Thus, it is suggested that applicant file the appropriate terminal disclaimer.

Note that Claims 30-35 are objected to as being dependent upon a rejected base claim 29, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

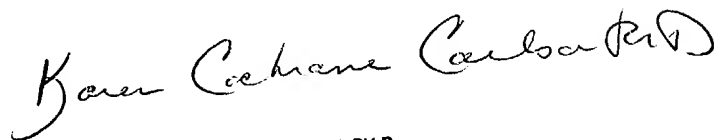
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.

July 8, 2004



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER